UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,779	04/05/2001	Nora Sarvetnick	18427-001 CON (SCRIPPS-1	1078

30623 7590 09/30/2002

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY
AND POPEO, P.C.
ONE FINANCIAL CENTER
BOSTON, MA 02111

EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	9

DATE MAILED: 09/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
826,779	SARVETNICK et al
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 7/17/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-21 is/are pending in the application.

Of the above claim(s) 1-12, 18-21 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 13-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☑ Claim(s) 1-21 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). ☐ Interview Summary, PTO-413

☑ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

Claims 1-21 are pending.

Applicant's election without traverse of Group VIII (claims 13-17) in Paper No. 7 filed on 7/17/02 is acknowledged.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Detection of proliferating cells in pancreatic ducts.

The specification is objected to because of the following informalities: at page 38, line 6 does applicant intend --identity-- in lieu of "identify"? At page 39, line 28 and page 41, line 5 it is considered that --(1993)-- rather than "(1994)" is the intended publication year. Applicant is referred to citation of this reference on attached Form 1449. Appropriate correction is required.

Claims 15 and 17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 15 recites nothing that further narrows the scope of claim 13. Both claims use same reagent and identify PDX-1 positive proliferating pancreatic cells. In like manner, claim 17 uses the same reagent and identifies the same type of proliferating cells as claim 16.

If applicant traverses the rejection he must explain how claims 15 and 17 each differ, by being narrower in scope, from their base claims.

Claims 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 13, step (b) and in claims 15 and 17 recitation of "contact" is confusing. Recitation of --binding-- in lieu of "the contact" would render step (b) of claim 13 consistent with what has been recited in step (a). Likewise recitation of --binding-- in lieu of "contact" in claims 15 and 17 would be appropriate.

Claims 13-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant's claimed invention of detecting proliferating cells in the pancreatic duct by detecting the contacting (binding) of anti PDX-1 antibodies to the proliferating cells is not enabled. Fernandes et al. (Endocrinology, 138, 1750, 1997) teach (page 1757, para. spanning cols. 1-2) that most of the pancreatic duct cells expressing PDX-1 and/or pancreatic hormones did not proliferate.

Therefore detecting PDX-1+ cells according to applicant's teachings would not permit one to conclude that these cells are proliferating. At most, applicant's teachings may only be applicable to the exemplified model system and not to other model systems, such as that exemplified by Fernandes et al.

Claims 13 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has not adequately described the genus of reagents that bind to PDX-1.

Specifically, applicant has not disclosed any such reagent except for an anti PDX-1 antibody. From the disclosure one would not even be able to envision the nature and the structure of any other kinds of agents (other proteins, carbohydrates, etc.) That would be those which would bind to PDX-1. As a species, an antibody to PDX-1 is not representative of the genus. The members of the claimed genus are not distinguished from other chemical products, except by function. No structural features commonly possessed by the members of the genus that distinguishes them from other chemical products have been described. Applicant thus did not possess the genus of reagents that bind to PDX-1. See Univ. of Calif. V. Eli Lilly and Co. 43 USPQ 1398.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13-17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicant's disclosure has not disclosed what one would do with the knowledge that there are proliferating pancreatic duct cells in a pancreas duct. In other words, why would one want to practice the claimed method in order to know this? The proliferation of pancreatic duct cells has not been correlated by applicant with the diagnosis of or the monitoring of the course of any pancreatic disease (e.g. diabetes, pancreatitis, pancreatic cancer, etc.). From applicant's disclosures at pages 21 and 41, applicant has used the information gained from his immunoelectron microscopic and immunohistochemical studies detecting proliferating pancreatic duct cells to conclude that INF gamma mediated pancreatic regeneration in the INF gamma transgenic mouse may follow mechanisms similar to those of fetal development. While this knowledge may be of interest to those in basic research, applicant has not disclosed how the claimed method would have any immediate and specific utility without further research. For example, applicant has pointed to no patients with any sort of condition that a physician would consider as candidates for having a tissue biopsy examined by the claimed process. Applicant has not indicated why, outside of basic research, anyone would be motivated to examine the pancreatic duct of an IFN gamma transgenic mouse by the claimed method.

Claims 13-17 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-17 are rejected under 35 U.S.C. 102(b) as being entirely anticipated by O'Reilly et al. (Diabetes, 46, 599, 1997).

O'Reilly et al. teach the immunohistochemical detection of IPF-1 (same as PDX-1, as disclosed by applicant at page 38) in the proliferating pancreatic duct of diabetic NOD mice. See Figure 4C and especially page 605, col. 1. Therein they teach that the IPF-1 cells may represent "early progenitors" which is consistent with the limitation of claims 16 and 17; in any event, from what applicant has now disclosed, at least some of the IPF-1 positive cells of O'Reilly et al. must have inherently been pancreatic stem/progenitors. Claims 15 and 17 are included since the examiner has indicated further supra that each of these recite nothing that further limits their base claims.

The following references are cited as of interest: Edlund (5,849,989) teaches (col. 30) immunohistochemical staining of tissues with antibodies to IPF-1 (same as PDX-1). He does not teach detection of proliferating pancreatic duct cells.

Habener et al. (5,858,973) disclose (cols. 10-11 and Figs. 4D-4F) immunohistochemical staining of pancreatic tissue with antibodies to IDX-1) (same as PDX-1). They do not disclose detection of proliferating pancreatic duct cells.

Fung et al. (6,326,201, which post-dates applicant's effective filing date) teach the immunocytochemical staining of cultured pancreatic duct cells (Fig. 3G) and of lectin sorted and cultured duct cells (Figs. 15-16).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

September 25, 2002

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644